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(54) **Blood air trap chamber**

Blutkammer mit Luftfalle

Poche de sang avec piège à air

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Description

BACKGROUND OF THE INVENTION

At the present time, hemodialysis or plasmapheresis blood chambers, so called air-trap blood chambers or "drip chambers" are typically made from two injection molded parts, comprising a round top cap which is solvent bonded to cylindrical chamber. Flow typically proceeds from a blood tube access port in the top cap out through an exit port at the bottom of the chamber. This structure has the following problems:

1. The two part assembly of top cap to cylindrical chamber is expensive and prone to leak, and the residual solvent adhesive is potentially toxic to the blood.
2. These top caps and chambers are generally round in cross section for injection molding and assembly reasons. Otherwise leaks will occur even more frequently. However, the round shape leaves barely sufficient room for the three to four ports which must communicate through the top cap to the interior of the drip chamber. These access ports must fit typically within a 15-18 mm. O.D. (outer diameter) area of the top cap, eliminating the chance of directly connecting a pump segment to a drip chamber, which typically is a 12 mm. O.D. tube placed in a port having an O.D. of about 14 mm.. Arterial drip chambers are always in close proximity to a pump segment but, because of the above, the drip chamber must be connected to the pump segment via a pump segment connector attached to a length of blood tube, the end of which can fit on the top cap. This is an expensive solution, also prone to leaks and high residuals of solvents.
3. Drip chambers are placed in arterial bloodlines either downstream of the pump segment ("post-pump") or upstream ("pre-pump"), depending on the prescription of the physician and the type of dialysis machine. Pre-pump arterial chamber bloodlines are more expensive to make because the IV saline port must often be mounted on a separate "T" connector upstream from the drip chamber. On "post-pump" bloodlines the IV saline port can be mounted on the inlet pump segment connector, thus saving one part and one tube and the assembly thereof. This combination connection also reduces leaks and solvent residuals.

There are a number of reasons why the IV saline port location is different in "pre-pump" and "post-pump" bloodlines, but each relates to the necessity of administering saline upstream from the arterial drip chamber:

a. During the priming procedure prior to dialysis, the arterial tubing upstream from the IV saline port must be retrograde primed. A drip chamber in this segment is difficult to [redacted]rade prime.

b. During dialysis, saline infusion (for relief of hypotension) is most safely done if any entrained bubbles are caught by a downstream arterial drip chamber. Also, the saline flow can only be visualized if there is a drip chamber downstream.

c. During rinse-back of blood to the patient at the end of dialysis, the arterial fistula and the arterial blood tube upstream from the IV saline port must be retrograde flushed with saline to return this blood to the patient. To counteract the resistance of blood pressure, the saline bag is typically squeezed to create retrograde saline flow. This resistance is much greater if a drip chamber is upstream from the IV saline port. (Note: rinse-back of the downstream portion of the arterial and venous lines is done by the blood pump so resistance in this direction is unimportant). Further, retrograde rinse of blood tubing is desirably of "plug flow" type, resulting in little saline being added to the patient. If a drip chamber is upstream from the IV saline port, the blood in the drip chamber is diluted slowly by saline, resulting in large amounts of saline being administered to the patient. This is a problem, since one of the goals of dialysis is to remove fluid from the patient.

One partial solution to the problems of arterial chamber has been the use of blow-molding to make one piece chambers. Thus, the two part assembly problems discussed above are eliminated. The other problems remain.

Also, the blowmolded chambers in the literature are all so-called "bottom entry" chambers whereby the blood inlet port is at the bottom of the chamber and blood enters into the blood space at the bottom or sidewall of the chamber. (This is opposite to "top entry" chambers, all injection molded so far, where blood enters at or adjacent the top into the airspace above the blood.) Two problems of the bottom entry chambers as disclosed in Swan U.S. Patent No. 4,681,606, Heath U.S. Patent No. 4,666,598 and European Patent Application No. 0058325A1 are:

the inlet port enters the blood space at a point higher than the outlet port, and
there is a diversion means to prevent inlet flow from breaking the surface of the blood space and causing foaming, such diversion directing the flow in the direction of the blood outlet.

The first problem is that blood must often be "rinsed-back" to the patient (at the end of dialysis) in a retrograde direction from the dialysis flow. With the inlet higher than the outlet, some blood will be caught in the chamber that cannot be returned to the chamber (the amount determined by the volume contained between

the inlet and outlet).

The second problem is that any entrained air in the inlet blood stream is directed toward the outlet, which under certain circumstances or today's higher blood flows can escape. As the primary function of the chamber is as an air trap, this is a significant problem.

It is an object of this invention to use blow molding to provide an IV saline port integral with the blood inlet of a chamber, thus eliminating the problems of a separate IV saline "T" connector construction as discussed above. A plastic blood chamber may be provided in which the blood flow can be run in either direction, for greater usefulness.

An inlet diverter that directs blood flow and entrained air away from the blood outlet, plus a chamber with equal height inlet and outlet for reversible flow efficiency, may be provided.

The chamber may be used in a pre-pump mode. In other embodiments, this same chamber can be connected in a post-pump mode, thereby reversing the flow direction and changing the pre-pump mode integral IV saline port into an integral heparin port.

The blood pump operates in the same direction for both manufactured blood lines in the pre-pump mode and the post-pump mode. In the pre-pump mode the blood chamber is under subatmospheric or negative pressure because the blood chamber is between the blood pump and the arterial fistula needle, which latter needle is the point of major flow resistance. In the post-pump mode the chamber is under superatmospheric or positive pressure since the chamber is between the pump and the venous fistula needle, which is another major point of flow resistance.

Physicians are sometimes worried about stressing a patient's fistula. Thus they like to use pre-pump designs because the negative pressure in the pre-pump tubing segments can be monitored, giving the doctor an idea of how much the patient's fistula is in danger of collapse.

In other situations, doctors worry more that the dialyzer will clot up, so they prefer to use post-pump designs because the positive pressure in the post-pump tubing segments can be monitored, giving the doctor an indication that the resistance in the dialyzer is increasing.

EP-A-134436 discloses apparatus for extracorpreal blood treatment in which an expansion chamber is connected to a blood line. The blood line includes a conduit which runs in spaced relation to the chamber along the full length of the chamber.

The present invention provides a haemodialysis set having a blood chamber device, the device being moulded from a plastics parison and having an elongate reservoir chamber for holding blood, the reservoir chamber having first and second blood ports to permit flow of blood into and out of the reservoir chamber, the first blood port being located at a lower end of the reservoir chamber, the blood chamber device including a conduit connecting at [illegible]per end with an IV solution or heparin access tube, the conduit extending downwardly along substantially the length of the reservoir chamber in spaced relation thereto and communicating at its lower end with the first blood port whereby, in use, the IV solution enters the reservoir chamber at a location below the level of blood in the reservoir chamber.

The blood chamber may have four or more separate conduits which are communicating directly with the chamber.

It is preferred for one conduit to connect directly with roller pump tubing for blood flow, with this connection being positioned adjacent the upper chamber end. The conduit may be of any desired transverse dimension to accommodate the connection with the roller pump tubing in a manner that does not crowd out the desired or necessary other access ports and apertures into the blood chamber.

It is also preferred for the first and second blood ports of the reservoir chamber to terminate inwardly at substantially identical longitudinal positions in the blood chamber. In other words, they occupy an "equal height" in the blood chamber, contrary from the current configuration in an arterial chamber for a dialysis set, where the blood inlet to the blood chamber is usually higher than the outlet. By the arrangement of this invention, it becomes practical to run the blood reversely through the arterial chamber, when and as that is desired, with effective operation and flow of blood therethrough, and without loss of a significant amount of blood within the arterial chamber. Thus, more blood can be returned to the patient in the back flush step of dialysis with reverse flow through the arterial chamber.

In one preferred embodiment especially in the pre-pump mode the inlet is positioned to divert blood flow away from the outlet.

In another preferred embodiment, the second blood port of the blood chamber communicates with a second conduit extending laterally along substantially the length of the reservoir chamber in spaced relation thereto. The reservoir chamber, the first conduit, and preferably the second conduit are all defined by a single, integral plastic blow moulding from a parison.

The second of the blood ports may be a pump segment access port (inlet or outlet) capable of mating with a blood pump tube of typically 9.0 to 14 mm. OD. This blood pump segment port can lead into the main cavity of the chamber at its bottom, side or top. Another access port or ports may be provided for pressure measurement, sample withdrawal or medication administration.

The first blood port is typically capable of mating with a plastic blood tube of typically 5.0 to 8.5 mm. OD. Flow in this chamber may be from blood tube to pump segment or vice versa (i.e. pre-pump or post-pump). Access ports for pressure measurement, sample withdrawal or medication administration may be provided at the upper end of the chamber, with the blood ports at

the bottom.

The plastic arterial chambers of this invention may be assembled into an arterial set for hemodialysis, or may be co-blow molded with a venous chamber to form a "cassette" that may be assembled into an arterial/venous set for hemodialysis.

A fluid flow chamber cassette is described by Heath et al. U.S. Patent No. 4,666,598. The following is an improvement on that invention.

A blowmolded chamber cassette results in fewer leaks, smoother blood pathways and lower manufacturing cost than the injection molded, front-to-back assembly of the Heath device.

Heath describes a cassette wherein transverse tubing ports must be employed, giving expense of construction as well as rough handling of the blood as it transits from axial direction to transverse direction.

Traditional peristaltic blood pumps are in the form of an upside-down U. This relates to the design of currently available blood chambers. Heath describes a bloodpump in the form of a backwards C, offering some benefits, but at the expense of complicated production method. We describe a blood pump in the form of an U, which has many benefits:

a. Unlike Heath, only one end of the pump segment need be tethered to the cassette, again reducing cost of construction. The pump segment is formed straight, and is curved by the curve of the stator of the pump housing. Heath, on the other hand, is curved into a backwards C by the presence on the cassette of two transverse mounted pump segment connectors. This complicates the molding and assembly methods required.

b. Unlike upside-down U pumps, the described U pump segment primes easily. Pump segments able to provide high bloodflow rates have large inner diameters, in the range of 8mm or more. In order not to crush delicate blood cells, peristaltic pump rollers are calibrated to leave a small gap between the pump segment walls when being crushed by the rollers. This gap, however, leaks air quite readily making it difficult for enough vacuum to be created to lift the initial column of saline up to prime the pump segment. With a U pump segment, gravity causes the saline to fall into the pump segment, thereby priming it.

c. A U blood pump easily allows bottom-entry, bottom exit arterial chamber, which is well known to handle rapid bloodflows with less turbulence and foaming than top-entry chambers.

DESCRIPTION OF THE DRAWINGS

Referring to the drawings, Figs. 1a and 1b are plan views of an arterial set, with blood chamber, of this invention, respectively in the pre-pump and post-pump modes, ready for connection with a conventional dialyzer and venous set;

Fig. 2 is an elevational view of the blood chamber as used in Fig. 1a, but in reversed position;

Fig. 3 is an elevational view of the blood chamber of Fig. 2 rotated 90° about its longitudinal axis;

Fig. 4 is a top plan view of the blood chamber of Fig. 2;

Fig. 5 is an elevational view of another design of blood chamber;

Fig. 6 is a top plan view of the blood chamber of Fig. 5;

Fig. 7 is an elevational view of the blood chamber of Fig. 5, rotated 90° about the longitudinal axis thereof;

Fig. 8 is an elevational view of another design of blood chamber;

Fig. 9 is an elevational view of a double blood chamber, made from a single flattened, plastic tube, to provide, for example, both the arterial and the venous blood chambers for a dialysis procedure in a single unit;

Fig. 10 is an elevational view of the blood chamber assembly of Fig. 9, rotated 90° about the longitudinal axis thereof;

Fig. 11 is a top plan view of the blood chamber of Fig. 9.

Fig. 12 is a partially schematic, fragmentary view of a dialysis set up showing a blowmolded, multiple chamber cassette similar to that shown in Figs. 9-11 mounted on a dialysis machine; and

Fig. 13 is a top view of the cassette of Fig. 12.

DESCRIPTION OF SPECIFIC EMBODIMENTS

Referring to Fig. 1a, an arterial pre-pump haemodialysis set 10 comprising a blood chamber device 28 is shown, along with a conventional hollow fiber dialyzer 12 and a conventional venous set 14, with the various parts being shown ready for assembly with each other in conventional manner. Apart from the novel disclosures herein, arterial set 10 is also shown of conventional design.

A liner lock patient arterial fistula needle connector 16 is provided on one end of arterial set 10 as shown, with the set tubing 18 extending through an on-off clamp 20, and injection site 22, extending to connect with

blood inlet via access po[redacted]f blood reservoir chamber 34 of blood chamber de[redacted]e 28.

Roller pump segment 26 is shown to directly connect with the blood outlet via access port 27 of blood reservoir chamber 34, and extends to a pump segment connector 49, and then to tube 30 extending to connector 32 for dialyzer 12. A heparin line 24 also connects to pump segment connector 49.

Venous set 14 has similar components as shown, which are of conventional design and thus do not need to be recited.

Referring to Fig. 1b, a similar arterial post-pump set 10a is shown, being of very similar design to the pre-pump set 10 except as otherwise described. A luer lock patient arterial fistula needle connector 16a, as before, is provided at one end of set 10a, with set tubing 18a extending through on - off clamp 20a and injection site 22a, in a manner similar to the previous set. However, in this embodiment, tubing 18a connects directly with pump tubing 26a. Heparin line 24a connects at the junction between tubings 18a, 26a, on the other end of pump tubing 26a because of the different pressure considerations in the post-pump mode. Heparin must always be administered against a positive pressure rather than a reduced pressure, to avoid the catastrophic occurrence of the heparin syringe discharging its entire contents in a few seconds into the patient in the event of heparin pump failure.

Pump tubing 26a communicates with blood reservoir chamber 34 of blood chamber device 28a at access port 27 of the chamber. It can be seen that chamber 34 may be the very same chamber as the one of blood chamber device 28, being merely reversed and with different connections. This provides a significant convenience in manufacturing and inventory control since the same reservoir chamber may be used in both situations without any change of design. Then, set tubing 30a communicates directly with access port 29 of blood reservoir chamber 34, terminating in a connector 32a as in the previous embodiment.

This setup may then communicate with a dialyzer 12 and a venous set 14 as in the previous embodiment.

Referring also to Figs. 2-4, blood chamber device 28 or 28a may be made, typically, through a blow molding process of a moderately stiff thermoplastic, as is known in the prior art so that there may be formed out of a single, plastic, tubular parison the following: a reservoir chamber 34, and a pair of conduits 36, 38 extending laterally along reservoir chamber 34, being spaced from the chamber by flat-sealed portions 40 of the plastic parison. Conduit 38 directly communicates with pump segment tube 26 through access port 27, with adequate room for such connection being available since the various access ports 27, 44, 50, 52 are distributed in a transverse line. Conduit 38 then extends the entire length of reservoir chamber 34 to communicate therewith at the lower end of chamber 34 through a second blood port 58.

Conduit 36 conn[redacted] branch-connection relation 42 with a first blood po[redacted]0 at the lower end of the reservoir chamber 34. Conduit 36 also extends the length of reservoir chamber 34, spaced therefrom by one of the flat seals 40 to a connector 44, for connection with a IV saline access tube in the pre-pump mode 46 having a conventional squeeze clamp 48. In the post-pump mode the tube 46a serves as a heparin tube.

Furthermore, at the end of blood reservoir chamber 34 which is remote from the first blood port 60, the additional access ports 50, 52 can be provided for respective connection with a pressure monitor line 54 and an air adjust or medication tube 56.

Reservoir chamber 34 is capable of flat-collapse under a predetermined suction pressure in the manner of prior art blood chambers for the known, desirable purposes.

Normally, blood is pumped by a roller pump from arterial patient connector 16 or 16a into reservoir chamber 34. From there, the blood flows out of the reservoir chamber, to pass through the remainder of the dialysis setup as shown in Fig. 1.

The first and second blood ports 60, 58 have inner ends separated by partition 61 which occupy substantially identical longitudinal positions along the blood chamber as particularly shown in Fig. 2, contrary to the prior art, where generally reservoir chambers have inlet ports that terminate deeper or higher within the reservoir chamber than the outlet port. It can be seen that in the pre-pump mode of Fig. 1a inner end of first blood port 60 serves as the inlet to the reservoir, and that the inlet is constructed to cause the inlet stream of blood to be directed laterally away from the second, outlet port 58 by means of a curvature in partition 61. The effect of this is to keep entrained air in the blood away from the outlet until the air bubbles have had a chance to rise to the top of the blood level and join an air bubble 63 typically found there.

Also because of this modification, it becomes possible to effectively and completely run blood in reverse through the system, by reversal of the roller pump that operates on pump tubing 26, so that blood can be returned to the patient through the arterial side as saline is added to the system, for example through tube 46 or 46a. Thus, at least some of the blood can flow back to the patient through connector 16 or 16a in a manner that is called "plug flow", by which it is meant that the blood does not mix to a large degree with the saline solution which is being used to replace it, so that the patient receives little more fluid than that which is found in his own blood, as the blood is returned to him or her from the dialysis set at the end of dialysis. This provides significant advantage to the dialysis procedure and the effective return of a maximum amount of blood to the patient after the dialysis procedure with a minimum of saline solution.

Referring to Figs. 5 through 7, another embodiment of blood chamber device for a dialysis set is disclosed.

Blood chamber device 64 m[illegible]made by blow molding as before, from a single, tubular parison to define a reservoir chamber 66 having at the bottom first and second blood ports 70, 68. Second port 68 may directly communicate with pump tubing 26a in a manner similar to the communication with pump tubing 26 in the previous embodiment, pre-pump mode, to provide blood flow out of chamber 66. Inlet flow of blood passes through first blood port 70 and blood conduit 30a in a manner analogous to the prior embodiment. This chamber may also be used in post-pump mode.

At the opposite end of blood chamber device 64, an access port 54a may be provided for the pressure monitor, while another access port 56a may be provided for air adjustment or the administration of medication.

An integral access tube 36a is also provided, being formed from the original, blow molded parison and integral with reservoir chamber 66 through a spaced, flattened, solid portion 40a of the original parison. Conduit 36a communicates at one end with an IV or saline tube 46a as in the previous embodiment, in pre-pump mode, extending laterally along the length of reservoir chamber 66 to join with first blood port 70 so as to be in communication with reservoir chamber 66. In post-pump mode, conduit 36a connects to a heparin line.

As before, an arterial hemodialysis set having a blood chamber of such a design is capable of backflushing of blood in chamber 66 and upstream therefrom back into the artery of the patient in a flow pattern which is reverse from the normal flow pattern, with good "plug flow" and the other advantages of such an arrangement. Also partition 61a is curved to facilitate bubble separation as described above.

Since the end of blood chamber 64 that carries the first and second blood ports 70, 68 has only two ports, it is possible to use second blood port 68 which has adequate size to directly receive pump segment 26a, for the advantageous elimination of an intermediate part and to reduce the number of solvent-sealed connections.

Referring to Fig. 8, another embodiment of this invention is shown, comprising a blood chamber device 74 which, as before, is made out of a single, tubular plastic parison by blow molding.

Blood chamber 76 is shown, having an upper end with a single access port 78, which may be used for connection with a pressure monitor, for example. A second connected conduit 80 is shown having a connection 82 with pump tubing 26b in a manner similar to the previous embodiments. Second conduit 80 then extends the entire length of reservoir chamber 76, making a U-turn 84 at the other end thereof into an open aperture forming a second blood port 102 and communicating with reservoir chamber 76.

A third, connected inlet conduit 86 is also provided on the other side of reservoir chamber 76, communicating at its upper end with blood tubing 30b in a manner similar to the previous embodiments through connector 88. Third, connected conduit 86 then extends the length of reservoir chamber 76, [illegible]integrally formed therewith through plastic web 87, [illegible]own to another U-turn 90, which communicates with the interior of blood chamber 76 as does first connected conduit 80, but via first blood port 100.

Thus, in the pre-pump mode blood is pumped through a set by means of a pump acting on pump tubing 26b, which is directly connected to second conduit 80. The blood passes through first conduit 86, and then enters reservoir chamber 76. The blood exits reservoir chamber 76 through second conduit 80, to travel on through the dialysis setup via blood tube 30b.

Additionally, a first connected tube 92 is formed out of the same parison by blow molding, to be integrally connected to the remainder of the blood chamber by plastic web 94, which like web 87, is a part of the parison. Connected tube 92 may be, in turn, connected to saline tubing 46b, with first conduit 92 extending the length of reservoir chamber 76, and joining with third, connected conduit 86 at a junction point 98, which is typically near curved portion 90. Thus, as before, blood can flow normally into reservoir chamber 76 through second connected conduit 80 and out of the chamber through third connected conduit 86.

Obvious modifications may be made for post-pump use. For reverse flow through reservoir chamber 76, in a manner similar to the embodiment of Fig. 2, the blood ports 100, 102 of the respective conduits 86, 80 terminate inwardly as shown at substantially identical longitudinal positions in the blood chamber 76, to permit easy reverse flow through the chamber. This provides advantages as previously discussed.

Turning to Figs. 9 through 11, in this embodiment of the blood chamber device, a single, blow-molded parison may form blood pre-pump arterial chamber 104 and venous chamber 106, for use in a combined arterial-venous hemodialysis set. Each of blood chambers 104, 106 defines a respective conduit 108, 110 which communicates with a first end 112, 114 of the reservoir chamber through a respective access port 116, 118.

In each case, the respective conduits 108, 110 are separated by flattened portions 120 of the parison from their respective chambers 104, 106 and each other, with the conduits extending laterally along substantially the length of each reservoir chamber 104, 106 in spaced relation thereto, in accordance with this invention.

Thus, a unitary, double chamber is provided for equipping a dialysis set with pre-pump and post-pump blood chambers, for example, or for any other desired use.

Access port 116 may be used for saline infusion when chamber 104 is under negative pressure and for heparin infusion if it is under positive pressure as in the post-pump mode. Blood port 128 may be in connection to the pump tubing, while blood port 130 comprises the arterial blood inlet. Access ports 122, 124 and 126 connect to pressure monitors or serve as medication application ports. Access port 118 connects from the venous

connector of the dialyzer, [redacted] blood port 132 connects to the venous patient connector. However, the multiple chamber cassette of this invention may be connected in other ways as desired.

Referring to Figs. 12 and 13, the cassette shown is made of a single blowmolded parison to define a pair of chambers 204, 206, similar in virtually all respects to the cassette of Figs. 9 through 11, and like reference numerals in the two hundreds corresponding to the same reference numerals in the one hundreds of the cassette of Figs. 9 through 11.

It can be seen that all tubing ports are substantially parallel with the long axis of cassette chambers 204, 206. This provides an improvement of easier handling of the blood over, for example, transverse entry ports.

Connected to blood port 228 is pump tubing 252, which is shown to be mounted in a roller pump housing 254 so that pump tubing 252 is maintained in a U-shaped configuration which is right-side up rather than upside down or on its side, as shown. The track of housing 254 defines the shape of the pump tubing 252. The roller pump with its arms 256 and rollers 258 functions in the known and normal manner to pump blood so that blood enters the system in one specific mode from the patient artery through blood inlet port 230 into chamber 204, and out of chamber 204 through port 228 into pump tubing 252. Then, the blood is pumped through tubing 260 to a dialyzer.

The blood from the dialyzer then enters tubing 262 to pass through access port 218 and separate conduit 210 to extend the length of venous chamber 206; to effect a U-turn 264, and to enter the venous chamber 206. Then, the blood passes through filter 250, through blood outlet port 232 and tubing 266 to pass back to the patient's venous system, while moving across ultra sonic air detector 268, and line clamp 270, both of conventional design.

By this embodiment, only one end of the pump segment 252 needs to be tethered to a cassette. This greatly reduces the cost of construction. The pump segment 252 may be formed straight, with the curvature being provided by the curve of the stator or track 254 of the pump housing.

Likewise, because the pump tubing 252 is formed in a right-side-up U segment, as described above, high blood flow rate tubing in the range of 8mm. inner diameter or more may be readily primed, since the segment readily fills with liquid and stays filled.

Also, such a blood pump allows the use of bottom entry, bottom exit arterial chamber 204, which is well known to handle rapid blood flows with less turbulence and foaming than top entry chambers.

Claims

1. A haemodialysis set having a blood chamber device (28,64,74); the device being moulded from a plastics parison and having an elongate reservoir chamber (34,66,[redacted] holding blood, the reservoir chamber (34,66,76) having first and second blood ports (60,58;70,68;100,102) to permit flow of blood into and out of the reservoir chamber, the first blood port (60,70,100) being located at a lower end of the chamber (34,66,76), the device including a conduit (36,36a,92) connecting at an upper end with an IV solution or heparin access tube (46,46a,46b), the conduit extending downwardly along substantially the length of the reservoir chamber (34,66) in spaced relation thereto and communicating at its lower end with the first blood port (60,70,100), whereby, in use, the IV solution enters the reservoir chamber at a location below the level of blood in the reservoir chamber.

2. The haemodialysis set of Claim 1 in which said reservoir chamber (34,66,76) is flattened.

3. The haemodialysis set of Claim 1 or 2 in which the second port (58,68,102) is also located at the lower end of the reservoir chamber (34,66,76) and communicates with a second conduit (38) extending downwardly along substantially the length of the reservoir chamber (34) in spaced relation thereto, the second conduit forming a part of the moulded blood chamber device (28,64,74).

4. The haemodialysis set of Claim 3 in which the moulded blood chamber device (74) includes a third conduit (86) which communicates with said first blood port (100) and which extends along substantially the length of said reservoir chamber (76).

5. The haemodialysis set of Claim 3 or 4 in which said second conduit (38,80) connects directly with roller pump tubing (26,26b).

6. The haemodialysis set of any preceding claim in which said first and second ports (60,58,70,68,100,102) terminate inwardly of the chamber (34,66,76) at substantially the same longitudinal position.

7. The haemodialysis set of Claim 6 in which a partition (61,61a) between the first and second ports (60,58,70,68,100,102) is angled relative to the length of the chamber (34,66,76) to cause inflow from one of said ports to be directed laterally away from the other of said ports, whereby air bubbles entering through the one of said ports are less likely to be immediately caught and sucked out of the chamber through the other of said ports.

8. A haemodialysis set according to any preceding claim, wherein the moulded blood chamber device includes flat sealed portions (40) interconnecting the reservoir chamber (34) with the or each conduit

(36) of the device.

9. A haemodialysis set according to Claim 1, wherein the moulded blood chamber device includes a second reservoir chamber (106) alongside the first reservoir chamber (104) and having third and fourth blood ports, the third of said ports being located at the lower end of the second chamber (106), the moulded blood chamber device including a further conduit (110) extending along substantially the length of the two chambers (104,106) and communication at its lower end with the third blood port.

10. Haemodialysis apparatus including an arterial haemodialysis set according to any one of Claims 1 to 9 and a venous haemodialysis set, the sets being connected with opposite sides of a dialyser, and a roller pump (252,256,258) having flexible tubing (252) connecting the dialyzer with the arterial set and including a roller (258) to collapse the tubing, the flexible pump tubing (252) being normally straight in its unstressed configuration, but formed into a configuration of an upright U-shape by mounting in a roller pump track (254), whereby the roller pump tubing is easily primed.

Patentansprüche

1. Hämodialysesatz mit einer Blutkammervorrichtung (28, 64, 74), welche Vorrichtung aus einem Kunststoff-Külbel geformt ist und eine langgestreckte Reservoirkammer (34, 66, 76) zum Aufnehmen von Blut aufweist, welche Reservoirkammer (34, 66, 76) erste und zweite Blutzulässe (60, 58; 70, 68; 100, 102) zur Ermöglichung einer Blutströmung in die und aus der Reservoirkammer aufweist, wobei der erste Blutzulaß (60, 70, 100) an einem unteren Ende der Kammer (34, 66, 76) angeordnet ist, wobei die Vorrichtung eine Leitung (36, 36a, 92) enthält, die an einem oberen Ende mit einem IV-Lösungs- oder Heparinzugangsschlauch (46, 46a, 46b) verbunden ist, welche Leitung sich abwärts über praktisch die Länge der Reservoirkammer (34, 66) in beabstandeter Beziehung dazu erstreckt und an ihrem unteren Ende mit dem ersten Blutzulaß (60, 70, 100) kommuniziert, so daß im Gebrauch die IV-Lösung an einer Stelle unter dem Spiegel des Bluts in der Reservoirkammer in letztere eintritt.

2. Hämodialysesatz nach Anspruch 1, wobei die Reservoirkammer (34, 66, 76) flachgedrückt ist.

3. Hämodialysesatz nach Anspruch 1 oder 2, wobei der zweite Zulaß (58, 68, 102) ebenfalls am unteren Ende der Reservoirkammer (36, 66, 76) angeordnet ist und mit einer zweiten Leitung (38) kommuniziert, die sich praktisch längs der Länge der Reservoirkammer (3[redacted]eabstandeter Beziehung dazu erstreckt, wobei [redacted]weite Leitung ein Teil der geformten Blutkammervorrichtung (28, 64, 74) bildet.

4. Hämodialysesatz nach Anspruch 3, wobei die geformte Blutkammervorrichtung (74) eine dritte Leitung (86) aufweist, die mit dem ersten Blutzulaß (100) kommuniziert und sich praktisch längs der Länge der Reservoirkammer (76) erstreckt.

5. Hämodialysesatz nach Anspruch 3 oder 4, wobei die zweite Leitung (38, 80) unmittelbar mit einer Rollenpumpenschlauchleitung (26, 26b) verbunden ist.

6. Hämodialysesatz nach einem der vorangehenden Ansprüche, wob ei die ersten und zweiten Zulässe (60, 58, 70, 68, 100, 102) einwärts (innerhalb) der Kammer (34, 66, 76) in im wesentlichen der gleichen Längsposition enden bzw. münden.

7. Hämodialysesatz nach Anspruch 6, wobei eine Trennwand (61, 61a) zwischen den ersten und zweiten Zulässen (60, 58, 70, 68, 100, 102) relativ zur Länge der Kammer (34, 66, 76) abgewinkelt ist, um eine Einströmung von einem der Zulässe seitlich oder quer vom anderen der Zulässe hinweg zu richten, so daß durch einen der Zulässe eintretende Luftblasen weniger wahrscheinlich unmittelbar abgefangen und über den anderen der Zulässe aus der Kammer abgesaugt werden.

8. Hämodialysesatz nach einem der vorangehenden Ansprüche, wobei die geformte Blutkammervorrichtung flache Versiegelungsabschnitte (40) aufweist, welche die Reservoirkammer (34) mit der oder jeder Leitung (36) der Vorrichtung verbinden.

9. Hämodialysesatz nach Anspruch 1, wobei die geformte Blutkammervorrichtung eine längs der ersten Reservoirkammer (104) gelegene zweite Reservoirkammer (106) mit dritten und vierten Blutzulässen aufweist, der dritte der Zulässe am unteren Ende der zweiten Kammer (106) angeordnet ist und die geformte Blutkammervorrichtung eine weitere Leitung (110) aufweist, die sich praktisch längs der Länge der beiden Kammern (104, 106) erstreckt und an ihrem unteren Ende mit dem dritten Blutzulaß kommuniziert.

10. Hämodialysevorrichtung mit einem arteriellen Hämodialysesatz nach einem der vorangehenden Ansprüche 1 bis 9 und einem Venen-Hämodialysesatz, welche Sätze mit gegenüberliegenden Seiten eines Dialysegeräts verbunden sind, sowie einer Rollenpumpe (252, 256, 258), die eine das Dialysegerät mit dem arteriellen Satz verbindende flexible

Schlauchleitung (252) eine Rolle (258) zum Zusammendrücken der Schlauchleitung aufweist, welche flexible Pumpenschlauchleitung in ihrer unbelasteten Konfiguration normalerweise geradlinig ist, aber bei Einbau in eine Rollenpumpenführung (254) in eine Konfiguration einer aufrechtstehenden U-Form verformbar ist, so daß die Rollenpumpenschlauchleitung einfach bzw. leicht vorrüllbar ist.

Revendications

1. Ensemble pour hémodialyse comportant un dispositif formant poche de sang (28, 64, 74) ; le dispositif étant moulé à partir d'une préforme en matière plastique et comportant une poche formant réservoir allongé (34, 66, 76) pour contenir du sang, la poche formant réservoir (34, 66, 76) comportant des premier et deuxième orifices à sang (60, 58 ; 70, 68 ; 100, 102) pour permettre un écoulement de sang à l'intérieur et hors de la poche formant réservoir, le premier orifice à sang (60, 70, 100) étant situé à une extrémité inférieure de la poche (34, 66, 76), le dispositif comprenant un conduit (36, 36a, 92) relié, à une extrémité supérieure, avec un tube d'accès (46, 46a, 46b) de solution IV ou d'héparine, le conduit s'étendant vers le bas, sensiblement sur la longueur de la poche formant réservoir (34, 66) dans une relation espacée de celle-ci et communicant, à son extrémité inférieure, avec le premier orifice à sang (60, 70, 100), ce par quoi, en utilisation, la solution IV pénètre dans la poche formant réservoir à un emplacement situé au-dessous du niveau de sang dans la poche de réservoir.

2. Ensemble pour hémodialyse selon la revendication 1, dans lequel ladite poche formant réservoir (34, 66, 76) est aplatie.

3. Ensemble pour hémodialyse selon la revendication 1 ou 2, dans lequel le deuxième orifice (58, 68, 102) est également situé à l'extrémité inférieure de la poche formant réservoir (34, 66, 76) et communique avec un deuxième conduit (38) s'étendant vers le bas, sensiblement sur la longueur de la poche formant réservoir (34) dans une relation espacée de celle-ci, le deuxième conduit faisant partie du dispositif moulé formant poche à sang (28, 64, 74).

4. Ensemble pour hémodialyse selon la revendication 3, dans lequel le dispositif moulé formant poche à sang (74) comprend un troisième conduit (86) qui communique avec ledit premier orifice à sang (100) et qui s'étend sensiblement sur la longueur de ladite poche formant réservoir (76).

5. Ensemble pour hémodialyse selon la revendication 3 ou 4, dans lequel ledit deuxième conduit (38, 80) est relié directement avec un tuyau souple (26, 26b) de pompe à rouleau.

6. Ensemble pour hémodialyse selon l'une quelconque des revendications précédentes, dans lequel lesdits premier et deuxième orifices (60, 58, 70, 68, 100, 102) se terminent à l'intérieur de la poche (34, 66, 76), sensiblement à la même position longitudinale.

7. Ensemble pour hémodialyse selon la revendication 6, dans lequel une séparation (61, 61a) située entre les premier et deuxième orifices (60, 58, 70, 68, 100, 102) forme un certain angle par rapport à la longueur de la poche (34, 66, 76) pour faire en sorte qu'un influx, à partir de l'un desdits orifices, soit dirigé latéralement en s'écartant de l'autre desdits orifices, ce par quoi des bulles d'air entrant par l'un desdits orifices risquent moins d'être immédiatement prises au piège et d'être aspirées hors de la poche par l'autre desdits orifices.

8. Ensemble pour hémodialyse selon l'une quelconque des revendications précédentes, dans lequel ledit dispositif moulé formant poche à sang comprend des parties plates hermétiques (40) reliant la poche formant réservoir (34) avec le, ou chaque, conduit (36) du dispositif.

9. Ensemble pour hémodialyse selon la revendication 1, dans lequel le dispositif moulé formant poche à sang comprend une seconde poche formant réservoir (106) le long de la première poche formant réservoir (104) et comportant des troisième et quatrième orifices à sang, le troisième desdits orifices étant situé à l'extrémité inférieure de la seconde poche (106), le dispositif moulé formant poche à sang comprenant un conduit supplémentaire (110) s'étendant sensiblement sur la longueur des deux poches (104, 106) et étant en communication, à son extrémité inférieure, avec le troisième orifice à sang.

10. Dispositif pour hémodialyse comprenant un ensemble pour hémodialyse artérielle selon l'une quelconque des revendications 1 à 9 et un ensemble pour hémodialyse veineuse, les ensembles étant reliés avec des côtés opposés d'un dialyseur, et une pompe à rouleau (252, 256, 258) comportant un tuyau souple (252) reliant le dialyseur à l'ensemble artériel et comprenant un rouleau (258) pour écraser le tuyau souple, le tuyau souple (252) de pompe étant normalement rectiligne dans sa configuration non contrainte, mais formé en une configuration de U vertical par montage dans un guide de pompe à rouleau (254), ce par quoi le tuyau de pompe à rouleau s'amorce facilement.

Fig. 1a

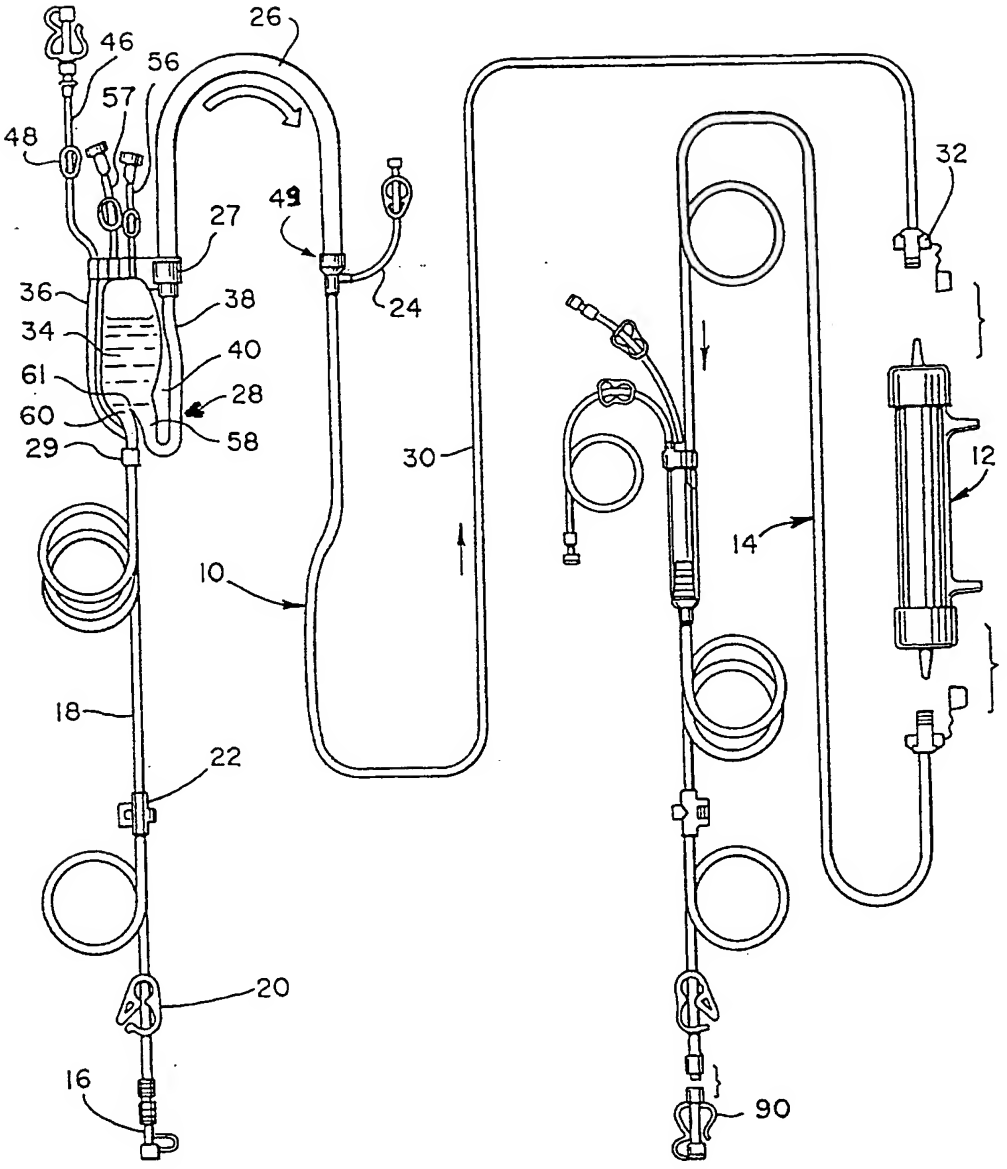
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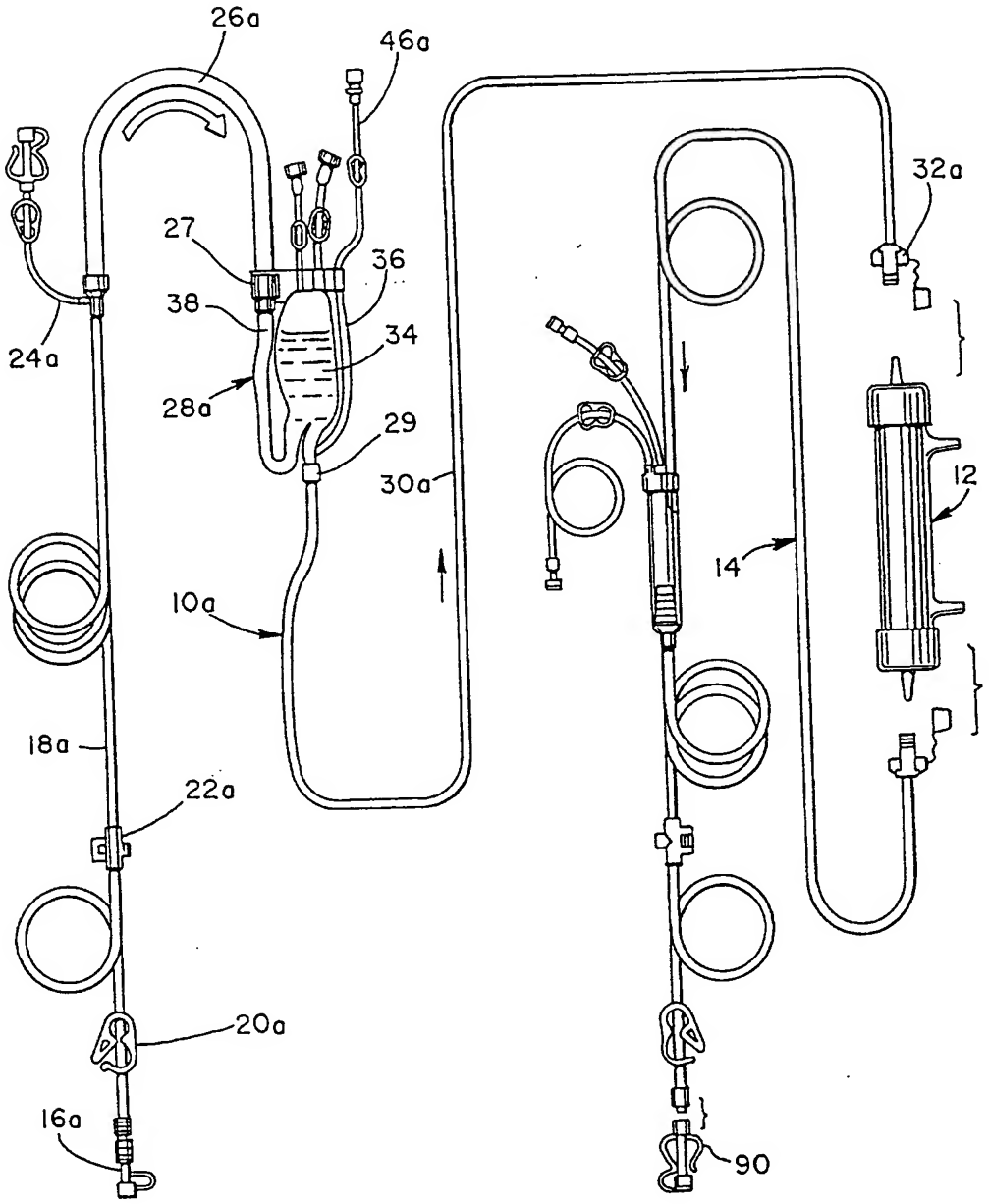
Fig. 1b



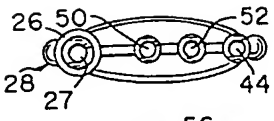


Fig. 4

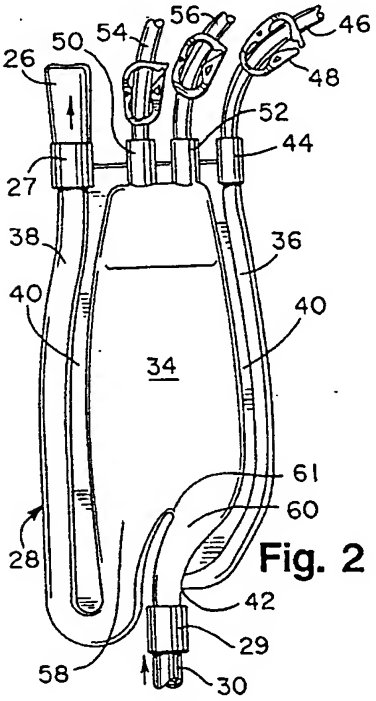
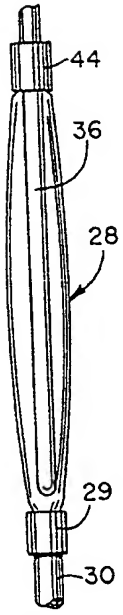


Fig. 2



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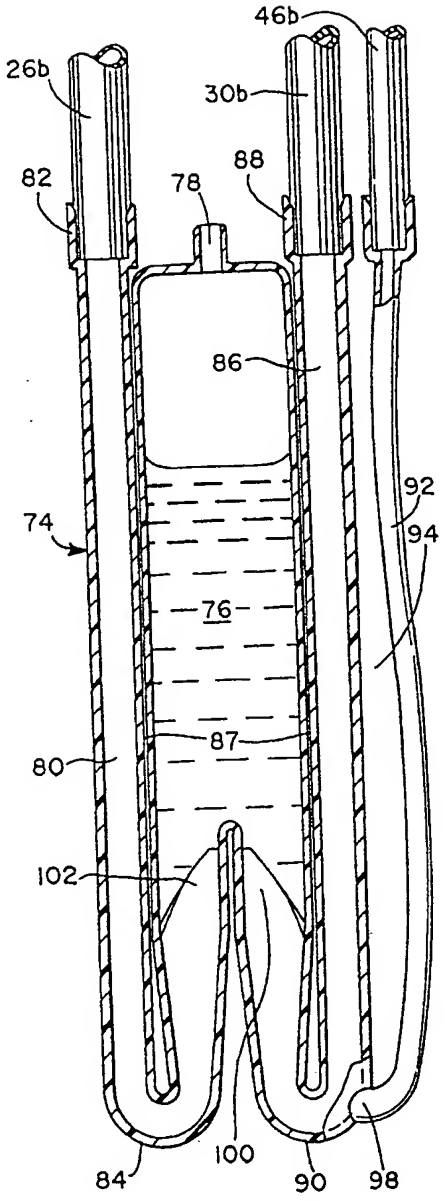
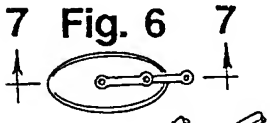


Fig. 8



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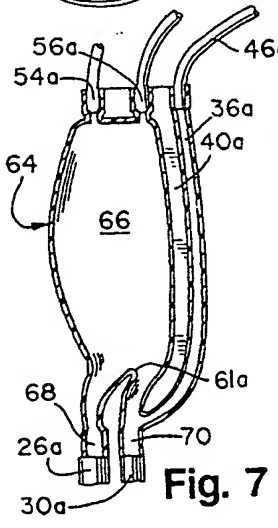

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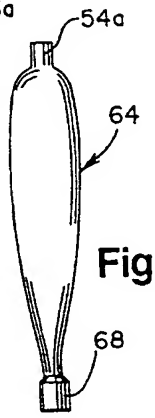

Fig. 5

Fig. 11

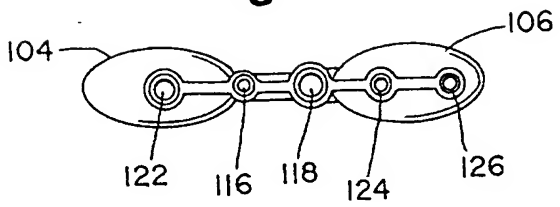

Fig. 9

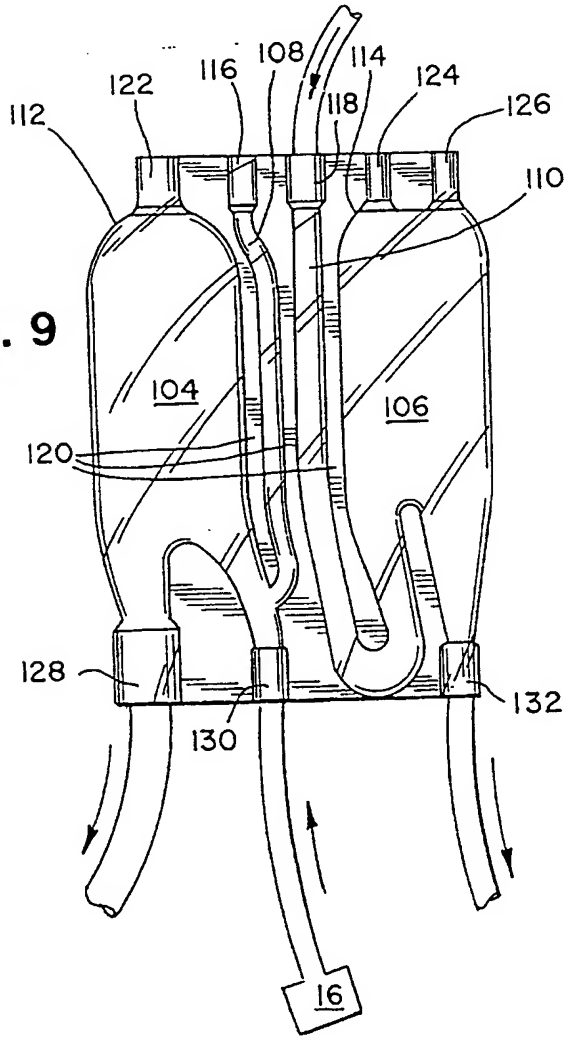

Fig. 10

Fig. 13

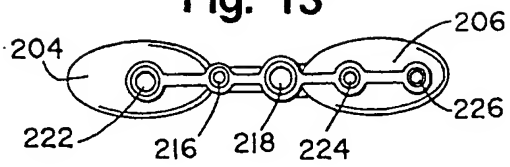
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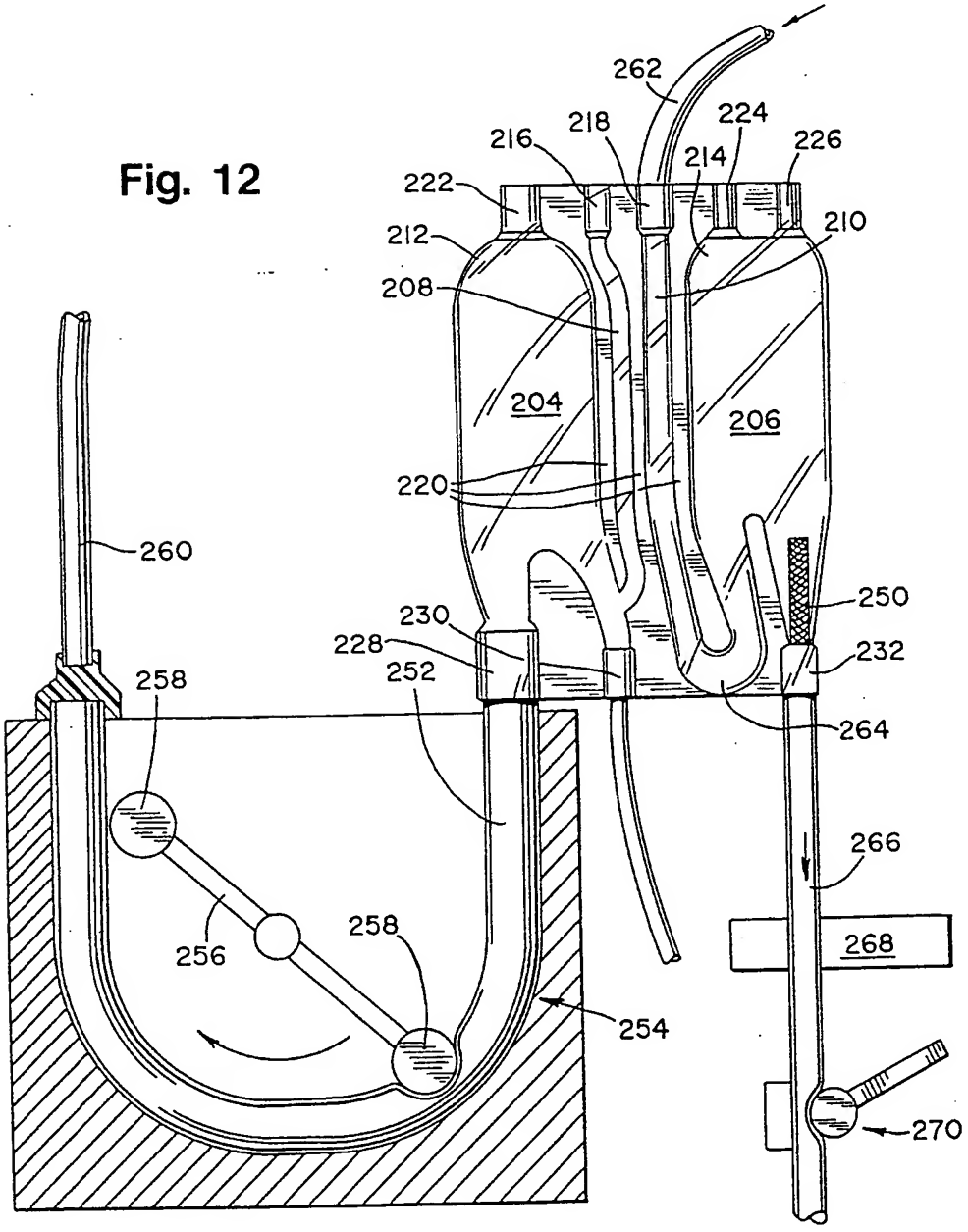
Fig. 12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